

Application No. : 10/721,607
Filing Date: November 25, 2003

REMARKS

The Applicants thank the Examiner for the careful and thoughtful examination of the present application. The foregoing amendments and the following remarks are responsive to the March 27, 2008 Office Action. By way of summary, Claims 1-23 were pending in this application. In the present amendment, the Applicants have amended Claims 1, 5, 7, 8, and 21. Accordingly, Claims 1-23 remain pending for consideration.

Allowable Subject Matter - Claims 9-20

The Applicants thank the Examiner for the indication of allowable subject matter in Claims 9-20.

Claims 15

Claim 15 originally recited, "The method of claim 14, wherein m is approximately -1.30." With the Preliminary Amendment filed November 4, 2005, the Applicants inadvertently introduced a typographical error into Claim 15, such that it read, "The method of claim 14, wherein m is approximately -0.1.30." As the Preliminary Amendment indicates, the Applicants only intended to add new Claims 21-23; they did not intend to amend Claim 15. Preliminary Amendment, page 6 ("Preliminary to the examination of the present application, please add new Claims 21-23."). With the present Amendment, the Applicants have corrected the typographical error to restore Claim 15 to its original form. Therefore, the status identifier of Claim 15 still indicates that this is an "original" claim. If the Examiner requires a different claim status identifier, the Applicants request instructions regarding the same, and the Applicants will amend the status identifier with the next communication.

Information Disclosure Statement

The Applicants submit an Information Disclosure Statement with this Amendment. The Applicants respectfully request the consideration of the Information Disclosure Statement and an indication of the same with the next Office communication.

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Objections To Claims 5 and 6

The Office Action objected to Claims 5 and 6 for minor informalities. In particular, the Office Action objected to the use of the term "for" in Claim 5. The Applicants have amended Claim 5 to clarify the claim language by using the phrase "corresponding with" instead of the term "for." Accordingly, the Applicants respectfully request withdrawal of the objections.

Rejection Of Claims 1-4 Under 35 U.S.C. § 112, ¶ 2

Claims 1-4 are rejected under 35 U.S.C. § 112, ¶ 2, as indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, Claim 1 is rejected because the Office Action stated that several of the claimed elements do not appear to define physical objects.

Claim 1 has been clarified, without altering its scope, to better identify the physical objects. These claim clarifications are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such clarifications. Claims 2-4 depend from Claim 1 and therefore include all of the features of Claim 1, including the clarification in this amendment. Accordingly, the Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-4 under 35 U.S.C. § 112, second paragraph.

Rejection Of Claims 1-3, 7, and 8 Under 35 U.S.C. § 102(e)

The Office Action rejected Claims 1-3, 7 and 8 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,846,190 to Woehrle. The Applicants respectfully traverse this rejection because Woehrle fails to identically teach every element of the claim. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

The Applicants respectfully submit that the claims as previously pending are patentably distinguished over the applied art. Claims 1, 7, and 8, however, have been amended in order to clarify their features. These claim amendments are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments.

Claims 1-3

As amended, Claim 1 recites (emphasis added):

1. A probe-off detector providing an indication that a physiological sensor may not be properly positioned proximate a tissue site, said probe-off detector comprising:

probe-off logic configured to receive a signal quality input indicative of an operating region of a sensor; and

a signal strength calculator configured to receive a sensor signal from the sensor and configured to generate a signal strength output dependent on a time-varying component of the sensor signal wherein the probe-off logic is further configured to provide a probe-off output based on a **comparison of the signal strength output and the signal quality input with a stored relationship defining an acceptable operating region of the sensor.**

The Office Action stated that "Woehrle teach[es] calculating a useful-to-noise-signal ratio and comparing the calculated value with a threshold to obtain a result indicative of whether the sensor is properly attached to a subject or whether the probe is off of the subject. An alarm is output when the calculated value is below the threshold." Office Action, Page 3. Woehrle, however, does not teach probe-off logic configured "to provide a probe off output based on a comparison of the signal strength output and the signal quality input with *a stored relationship defining an acceptable operating region of the sensor.*" At most, Woehrle teaches comparing the calculated value with a threshold value.

The Applicants, therefore, submit that Woehrle does not identically teach or suggest every element of amended Claim 1. Moreover, Woehrle does not identically teach or suggest every element of dependent Claims 2 and 3 based on their dependency from Claim 1 and because of the additional features recited therein. Accordingly, the Applicants respectfully request that the Examiner withdraw the rejection of Claims 1 and 3 and allow these claims.

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Claims 7 and 8

As amended, Claim 7 recites (emphasis added):

7. A detector for determining when a physiological sensor may not be properly positioned with respect to a measurement site, the detector comprising a signal strength calculator which processes an input signal expected to be representative of at least one parameter measured by a physiological sensor, to produce an output representative of a strength of the input signal; and logic which indicates that the input signal may not represent the parameter when a predetermined portion of the output is below **a signal strength limit for a corresponding signal quality value.**

Woehrle, however, does not teach "logic which indicates that the input signal may not represent the parameter when a predetermined portion of the output is below a signal strength limit for a corresponding signal quality value." At most, Woehrle teaches comparing the calculated value with a threshold value.

The Applicants, therefore, submit that Woehrle does not identically teach or suggest every element of amended Claim 7. Moreover, Woehrle does not identically teach or suggest every element of dependent Claim 8 based on its dependency from Claim 7 and because of the additional features recited therein. Accordingly, the Applicants respectfully request that the Examiner withdraw the rejection of Claims 7 and 8 and allow these claims.

Rejection Of Claims 21-23 Under 35 U.S.C. § 102(e)

The Office Action rejected Claims 21-23 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,035,223 issued to Baker, Jr., (Baker). The Applicants respectfully traverse this rejection because Baker fails to identically teach every element of the claim. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

The Applicants respectfully submit that the claims as previously pending are patentably distinguished over Baker. Claim 21, however, has been amended in order to clarify the features of the Applicants' inventions. These claim amendments are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments.

Claims 21-23

As amended, Claim 21 recites (emphasis added):

21. A method of determining a sensor off condition for physiological monitoring system, comprising:

receiving first and second intensity signals from a light-sensitive detector in the sensor which detects light of at least first and second wavelengths attenuated by body tissue carrying pulsing blood;

determining a plurality of signal characteristics of the first and second intensity signals originating from the sensor; and

analyzing the plurality of signal characteristics to determine the sensor off condition **based upon a stored relationship between signal strength of said intensity signals and at least one of said signal characteristics.**

The Office Action stated that “Baker teaches a method in which measured data is used to compute seven ‘metrics’ which are analyzed to determine if the measurement probe is properly attached to the subject.” Office Action, Page 3. Baker, however, does not teach at least “analyzing the plurality of signal characteristics to determine the sensor off condition based upon a stored relationship between signal strength of said intensity signals and at least one of said signal characteristics.” Instead, Baker merely describes using a neural net and seven metrics including (1) “the average IR AC amplitude”, (2) “the relative variability of the IR AC amplitude”, (3) “the degree to which the IR and Red AC-coupled waveforms are correlated”, (4) “the variability of the IR DC light level”, (5) “the bias or slope of the IR DC light level”, (6) “the pulse shape”, and (7) “harmonicity” which “is computed from the IR waveform after it has been bandpass filtered, normalized, and whitened, where the whitening filter is a first difference filter.” Baker Col. 6, Ln. 23 – Col. 9, Ln. 30.

The Applicants, therefore, submit that Baker does not identically teach or suggest every element of amended Claim 21. Moreover, Baker does not identically teach or suggest every element of dependent Claims 22 and 23 based on their dependency from Claim 21 and because of the additional features recited therein. Accordingly, the Applicants respectfully request that the Examiner withdraw the rejection of Claims 21-23 and allow these claims.

Double Patenting

Claims 1, 5, and 6 stand rejected on the ground of non-statutory, obviousness-type double patenting as unpatentable over Claims 1 and 2 of U.S. Patent No. 6,360,114.¹ While the Applicants traverse the rejection, and do not acquiesce, in order to expedite prosecution, the Applicants have timely-filed a terminal disclaimer, thus rendering the rejection moot. Accordingly, the Applicants respectfully request withdrawal of the non-statutory, obviousness-type double patenting rejection with respect to the rejected claims.

Examiner's Statement of Reasons for Allowance

The Applicants respectfully disagree with the Examiner's Statement of Reasons for Allowance to the extent that not all the claims include the method steps mentioned by the Examiner's Statement. Also, to the extent that there is any implication that the patentability of the claims rests on the recitation of a single feature, Applicants respectfully disagree with the Examiner's Statement because it is the combination of features that makes the claims patentable. For example, Claims 5 and 9 recite:

5. A method of detecting that a pulse oximetry sensor may not be properly attached to a tissue site by processing a sensor signal, the method comprising:

determining a signal strength limit dependent on a processor input;
calculating a signal strength value from a sensor signal of a pulse oximetry sensor;
calculating a signal quality value of the sensor signal; and
indicating a probe-off condition when the signal strength value is below the signal strength limit corresponding with the signal quality value.

9. A method of determining whether a pulse oximetry sensor is properly connected to a patient, said method comprising the steps of:
receiving a signal strength vector;

¹ The Office Action actually indicates that the double patenting rejection is based upon U.S. Patent No. 6,260,114, but the Applicants believe that this may be an inadvertent typographical error. The Applicants request clarification from the Examiner (and request that the attached terminal disclaimer is not entered) if the Applicants' understanding is incorrect.

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receiving at least one of a signal strength limit and a pulse rate density;
providing an indication of poor signal strength based on said signal strength vector and said at least one of a signal strength limit and a pulse rate density; and
determining whether a pulse oximetry sensor is properly connected to a patient based at least in part on the indication.

Accordingly, the Applicants submit that Claims 5 and 9 are allowable because the applied art does not teach or suggest the combinations of features as recited by these claims. Likewise, the other claims of the present application are also allowable because they each recite a combination of features that are not taught or suggested by the applied art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Request For Telephone Interview

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicants' undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicants' attorney can be reached at (949) 721-7608 or at the number listed below.

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Conclusion

For at least the foregoing reasons, the Applicants submit that Claims 1-23 are in condition for allowance, and the Applicants respectfully request allowance of the same.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 25, 2008

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